EXHIBIT F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 413, 430 and 447

45 CFR Parts 1 and 19

[BERC-356-F]

Medicare and Medicaid Programs; Limits on Payments for Drugs

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This rule eliminates current Departmental procedures for setting limits on payments for drugs supplied under certain Federal health programs; and revises Medicaid rules concerning the methodology for determining upper limits for drug reimbursement. This rule enables the Federal and State governments to take advantage of savings that are currently available in the marketplace for multiple source drugs. It also maintains State flexibility in the administration of the Medicaid program.

EFFECTIVE DATE: The regulations are effective October 29, 1987. State agencies have 90 days from the publication date of this regulation until the effective date in which to submit a State plan amendment and the required attachment.

FOR FURTHER INFORMATION CONTACT: Anthony Lovecchio, (301) 594-4010.

SUPPLEMENTARY INFORMATION:

I. Background

A. Existing System

In 1976, the Department implemented drug reimbursement rules at 45 CFR Part 19 under the authority of statutes pertaining to upper payment limits for Medicaid and other programs. The authority to set an upper payment limit for services available under the Medicaid program is provided under section 1902(a)(30)(A) of the Social Security Act.

The Department rules are intended to ensure that the Federal government acts as a prudent buyer of drugs under certain Federal health programs. The rules set limits on payments for drugs supplied under Medicaid and other programs. Of the Federal programs involved, these rules have the greatest impact on the Medicaid program. Specifically, these regulations provide that the amount the Department recognizes for drug reimbursement or payment purposes will not exceed the lowest of—

- The maximum allowable cost (MAC) of the drug, as established by HCFA's Pharmaceutical Reimbursement Board for certain multiple source drugs (generic drugs), plus a reasonable dispensing fee;
- The estimated acquisition cost (EAC) of the drug (the price generally and currently paid by providers for a particular drug in the package size most frequently purchased by providers), as determined by the program agency, plus a reasonable dispensing fee; or
- The provider's usual and customary charge to the public for the drug.

The regulations provide that the MAC will not apply if the prescriber has certified in his own handwriting that a specific brand of that drug is medically necessary for the patient.

The regulations at 45 CFR Part 19 also establish within HCFA a Pharmaceutical Reimbursement Board (PRB). The PRB identifies multiple source drugs for which significant amounts of Federal funds are or may be expended and is responsible for establishing the MAC for those drugs. The process by which a MAC is established includes PRB consultation with the Food and Drug Administration (FDA), opportunity for public comment on a proposed notice of the MAC limit published in the **Federal Register**, a public hearing, and publication of the final MAC determination in the **Federal Register**. The PRB sets the MAC at the lowest unit price at which the drug is widely and consistently available. In addition to limiting the level of payment for multiple source drugs, the MAC program tends to promote substitution of lower cost (generic) drug products for brand-name drugs, since the latter are frequently available only at prices higher than the MAC limits.

Similar to the Department regulations (45 CFR Part 19) that set limits to Federal payments for drugs are the Medicaid regulations at 42 CFR 447.331 through 447.334. The regulations at §§ 447.331 through 447.334 limit the amounts that State Medicaid agencies may claim for Federal matching purposes under the Medicaid program. These limits are the same as those specified in 45 CFR Part 19. Thus, the Medicaid agency must claim no more for each drug than the lowest of —

- The MAC of the drug, as established by the HCFA PRB for certain multiple source drugs, plus a reasonable dispensing fee;
- The EAC of the drug (that is, the Medicaid State agency's best estimate of the price generally paid by providers) plus a reasonable dispensing fee; or
- The provider's usual and customary charge to the public for the drug.

The Medicaid regulations also provide that the MAC will not apply if the prescriber has certified in his own handwriting that a certain brand of that drug is medically necessary for the patient.

B. Problems and Concerns

In 1983, a Departmental Task Force was established to review the Department's drug reimbursement regulations at 45 CFR Part 19. Specific concerns presented to the Task Force included—

- The quality of multiple source drugs;
- The interpretation of "widely and consistently available" as related to the process used by the PRB in setting MAC limits;
- The adequacy of drug reimbursement; and
- Problems in administering the MAC and EAC programs (for example, the short time that the Medicaid agencies have to implement MAC limits once they become effective, and the lack of a mechanism for raising the MAC limits quickly when necessary due to changes in the market).

We agree that the process of approving a MAC for a specific drug is lengthy. This has been of concern particularly since the passage of the Drug Price Competition and Patent Term Extension Act of 1984 (Pub. L. 98-417). This law streamlines the FDA approval process for certain drugs. The result of this law is that therapeutically equivalent (generic) drugs will be coming into the marketplace more quickly than in the past. As evidenced by the current MAC program, we are interested in encouraging the use of therapeutically equivalent drugs. We would like to adopt a Medicaid drug policy that would allow us promptly to adjust payment upper limits to reflect the availability of new drug equivalents as they enter the marketplace.

Based on the concerns addressed above and the Department's desire to take advantage of savings that are currently available in the marketplace for multiple source drugs, we published a Notice of Proposed Rulemaking (NPRM) on August 19, 1986 (51 FR 29560). The NPRM announced proposed revisions to our procedures for establishing upper limits for drug payments and provided a 30-day public comment period. On September 18, 1986, we published a second notice in the **Federal Register** (51 FR 33086) announcing an extension of the comment period, the availability of new data to anyone wishing to perform an

[illegible]n lower cost therapeutically equivalent drugs.

B. State Plans

Comment: Many commenters thought that if a State agency wished to use an alternative payment system to the one that would be established as the upper limit standard, the agency would have to secure a program waiver under the provisions of section 1915 of the Act. The perception was that this process was very rigorous and entailed considerable State efforts for justifying the waiver.

Response: It was our intent that, regardless of whether a State agency follows the approach established by HCFA or uses an alternative drug payment system, a State agency would not be required to obtain a program waiver. The NPRM proposed a process under which a State agency would be free to establish any payment system it would choose (except when freedom of choice or provider contracting is involved which would then require a waiver). The State agency must describe the methodology in its State plan which is subject to the usual State plan approval process.

Because the proposed language regarding the State plan approval process caused some confusion, we are revising it to make clear that drug payment methodologies must conform to all State plan requirements as must any other service. Under this final rule, we are clarifying that all State agencies are required to: (1) Describe comprehensively the agency's payment methodology for prescription drugs in its State plan; (2) make two findings, one for therapeutically equivalent multiple source drugs and one for all other drugs, through mathematical computation, analysis and comparison to determine that the payment levels under its payment methodology will not exceed the payment levels that would result from the application of the system promulgated by HCFA as the upper limit; (3) make an assurance to us that it has made such findings; and (4) maintain and make available to HCFA, upon request, documentation to support the finding.

The agency's assurance will serve as the basis for the approval of the State plan. The agency findings will be monitored through State assessments and other evaluations or auditing procedures to review the State documentation underlying the assurance without the need for specialized annual reporting by the States. Consistent with other aspects of the Medicaid program, if HCFA finds a problem with a State's assurance, HCFA can request the State to provide data to support its assurance and, if appropriate, HCFA will disallow FFP or consider whether the State ought to be subject to the statute's compliance procedures.

C. Implementation of PhIP or CIP

Comment: Many commenters expressed confusion or raised questions about the absence of operational details for PhIP and CIP. States were particularly concerned about the significant changes that would occur in current operations (for example, data collection, programming modifications, payment screens, monitoring price changes) and accompanying costs, to implement PhIP or CIP.

Response: We deliberately did not include specific technical details in the NPRM because the objective of the proposals was to establish a methodology for setting a standard for Medicaid upper payment limits for purposes of FFP. We did not intend to set forth or describe the intricate details of a particular payment system. Nonetheless, we did set forth a sufficient amount of technical detail to allow commenters to identify potential problems and solutions, and we took these into account in reaching the final decision. We do not intend to impose unnecessary or expensive operational requirements on States. Rather, it was our intent to permit State agencies to exercise maximum flexibility in designing a payment system subject only to the maximum payment levels established by this regulation.

D. Availability and Quality of Drugs

Comment: Several commenters wrote requesting that we demonstrate that the availability and quality of drugs would not be adversely affected under the proposed Medicaid drug reform alternatives.

Response: It is our belief that the application of the 150 percent upper limit standard that we are adopting for certain multiple source drugs will yield a payment level that will be great enough to assure widespread availability of drug products. Furthermore, because we are implementing aggregate upper limit standards on the State's Medicaid payments (expenditures) for drugs, a State will have the ability to make payment at levels above the specific standard for certain drugs, provided that the agency makes the payment at levels below the specific standard for other drug products. This added State flexibility will virtually guarantee widespread availability of all affected drugs provided that the State agency can determine that in the aggregate for those drugs, the State achieved savings equal to or greater than the HCFA upper limit standard.

In reference to the quality of those multiple source drugs to which we will apply the 150 percent markup, we believe that the FDA assurance that all of the formulations it has approved have been evaluated as therapeutically equivalent in the most current edition of their publication "Approved Drug Products with Therapeutic Equivalence Evaluations" is adequate.

E. Additional Compendia

Comment: One commenter requested inclusion of its publication, which is a national compendium of drug cost information, among the publications that will be used in determining the upper limit payment for multiple source drugs.

Response: We agree with the commenter that publications other than the *Red Book* and *Blue Book*, which were the only sources we proposed to use, can be used. Thus, we are revising the regulations. The final rules will state that in determining the upper limit payment levels for multiple source drugs, we will select from all available national compendia of drug cost information that reflect drug prices and availability on a national level. As we publish these upper limits in State Medicaid program issuances, we will identify the source of our drug price information. We periodically will publish these upper limits in our *Medicaid Manual* to assure comprehensive knowledge of upper limits for multiple source drugs and to reduce the need for State agencies to do independent research and computation.

F. Dispensing Fees

Comment: Several commenters suggested that either we delete the requirement in current regulations for State surveys of dispensing fee costs or require State agencies to update these fees in a periodic manner.

Response. In the interest of State flexibility and to avoid imposing unnecessary Federal procedural requirements as to how State agencies establish such fees, we are deleting the current requirement at § 447.333 regarding dispensing fees. State agencies will still be required to determine reasonable dispensing fees or, if dispensing fees are not paid separately, to impute an amount equivalent to a reasonable dispensing fee, in order to include those amounts in the calculations and comparisons they make to meet the upper limit standard for FFP. We expect that most States will continue their present activities to establish a reasonable dispensing fee

level and will document these and any new activities in their State plan. Such activities could include: (1) Audits and surveys of pharmacy operational costs; (2) compilation of data regarding professional salaries and fees; and, (3) analysis of compiled data regarding pharmacy overhead costs, profits, etc.

G. Use of "Smart Cards" and "Vouchers"

Comment: Several commenters suggested that HCFA adopt the use of a "smart card" or "voucher" payment system for payment of prescription drug claims. These commenters indicated that these systems would save significant amounts of expenditures.

Response: As we noted in the preamble to the NPRM, the use of a voucher or bank draft payment (smart card) system by State agencies was not one of the issues addressed in the proposal to establish upper payment limits. The methodology of determining an upper limit for prescription drug payments was the subject of the NPRM, not the claims payment process. The use of a voucher or "smart card" claims payment system is something which State agencies may do at present. If State agencies determine that such a system to process claims is workable, efficient and more cost-effective than their current system, and that system meets Medicaid program requirements, then, indeed, we encourage the individual agencies to adopt such a claims payment system.

H. Physician's Override

Comment. Several commenters recommended that we delete the physician override requirement while one State agency recommended that we strengthen the requirement.

Response. We are retaining the physician override requirement as proposed in the NPRM. This requirement is a safeguard that assures that the physician can select the drug that is medically necessary and best suited for his or her patient. This means that the upper limits established for specific (listed) multiple source drugs will not apply if the prescribing physician certifies that a brand name drug is medically necessary. These payments will not be included in the calculation for compliance with the upper limit for multiple source drugs. Instead, in these instances, the upper limit for all other (non-listed) drugs will apply. As under current regulations, a State agency may choose to elaborate and be more stringent regarding this standard if it chooses.

I. Acceptable Upper Limit Assurance

Comment: Several State agencies asked for guidance in making annual findings regarding the upper limit determinations and in deciding what constitutes an adequate assurance regarding the upper limit determinations when proposing State plan amendments.

Response: We are requiring in the final rule two findings. We are requiring an annual finding relating specifically to the multiple source drugs which HCFA will identify through Medicaid program issuances.

We also are requiring a separate triennial finding relating to the category of "other drugs".

The finding for the listed multiple source drugs will confirm that the agency's payment rates for these drugs do not exceed the aggregate payment levels determined by applying the upper limit formula plus a dispensing fee. The finding for the category of "other drugs" will confirm that a State agency's aggregate expenditures for these drugs under their chosen payment methodology, will not exceed aggregate payment under the EAC criteria that are retained for this rule. (Under this rule, the EAC criteria are applied as an upper limit on an aggregate basis rather than on a prescription by prescription basis.) The findings for both the listed multiple source drugs or "other drugs" can be supported by any documented acceptable method of sampling, imputation and statistical analysis that the State agency uses in making its determination. The State agency will then make an assurance to HCFA that it has made the required findings. That assurance to HCFA will constitute a presumption of validity of the findings and will serve as the basis for approval of the State plan.

J. Phase-In Upper Limit Standard for Multiple Source Drugs

Comment: One State agency recommended that the upper limit standard for multiple source drugs consist of between 15–20 specific limits established at 60 day intervals. The agency is concerned about having sufficient lead-time for wholesalers and pharmacies to adjust inventories to comply with the upper limit standard.

Response. We believe that we are providing an adequate period of time for these adjustments to occur. These regulations are effective October 29, 1987. This allows State agencies 90 days from the date of publication to the effective date of these final regulations in which to submit their plan amendment and required attachment.

K. Impact Analysis

Comment: Several commenters criticized us for not providing sufficient detail in our impact analysis to permit a comparison of the relative effects of the three alternatives presented in the NPRM. In particular, one commenter stated that we failed to support our contentions that all three proposals would reduce "disruptions" of drugs to retail outlets and achieve substantial savings through encouraging the use of low cost generic substitutions.

Response: As we explain in section V. of this preamble, the combination of having to analyze an extremely complex industry with very little data makes it difficult to formulate a comprehensive empirically grounded impact analysis. Based on the information available to us at the time of the NPRM, we did not expect any of the three proposals offered in the NPRM to have an annual effect on the economy of $100 million or more. Thus, we were not required under Executive Order 12291 to propose an impact analysis. Yet, because we were concerned, at the time the NPRM was published, that one or more of the proposals might have an annual effect of $100 million or more, and because we expected our proposals to generate considerable public debate, we voluntarily prepared an analysis that met the criteria of the Executive Order.

Comment: One commenter claimed that in our impact analysis, we failed to evaluate the effects of our proposals on the research and development of new drugs.

Response: It is far from clear to us what impact our proposals would have on the research and development of new drugs. These proposals are attempts on our part to take advantage of the competitive forces at work in the marketplace.

Companies that develop new drugs are provided protection under patent from competition for a certain period of time during which they may charge prices high enough, presumably, to recover their development costs associated with the drug in question or to subsidize the research and development costs of other drugs. Once the patent expires, however, other pharmaceutical firms may copy the drug, and once approved by the FDA, they may market the same drug and set their own price. Our proposals were designed to take advantage of this competition among drugs that are no longer under patent and not intended to prevent the development of new drugs. We were merely seeking to participate in the market as prudent buyers.

L. Application to Medicare

Comment: One commenter specifically requested clarification that the alternative selected by the Department for the final rule would not apply to the Medicare program and that hospitals and hospital-based skilled nursing facilities would be exempt under Medicare.

Response: As we stated in the NPRM, we are deleting the references to the MAC program contained in the Medicare regulations concerning allowable costs for drugs. (In the NPRM, we noted that we would delete § 405.433. However, that regulation has since been redesignated and is now located at § 413.110. Thus, in this final rule, we are deleting § 413.110.) The upper limits for drugs contained in this final rule pertain only to the Medicaid program. They do not apply to hospitals and hospital-based skilled nursing facilities under Medicare.

IV. Provisions of the Final Regulations

In this final rule, we have attempted to: (1) Respond to the public comments on the NPRM; (2) provide maximum flexibility to the States in their administration of the Medicaid program; (3) provide responsible, but not burdensome Federal oversight of the Medicaid program; and, (4) take advantage of savings resulting from the availability of less costly, but safe and effective, generic drug substitutes.

To accomplish this, we are drawing from various aspects of the proposals. The Federal upper limit standard we are adopting for certain multiple source drugs is based on the application of a specific formula similar to that described in the NPRM. The upper limit for other drugs is similar to that in the NPRM in that it retains the EAC limits as the upper limit standard that State agencies must meet. However, this standard is applied on an aggregate rather than on a prescription specific basis.

We want to emphasize that as a result of our adopting aggregate limits as the upper limit standards, State agencies are encouraged to exercise maximum State flexibility in establishing their own payment methodologies. We do not intend that our adoption of the formula approach to set limits for multiple source drugs be construed as an indicator of the Federally preferred payment system. The use of the formula approach is primarily due to the straight-forward application and administrative ease in setting upper limits. We encourage State agencies to establish any program that will substitute lower-priced alternatives for drugs. We hope that the State agencies will be innovative in these programs and find ways to assure the availability at reasonable prices of multiple-source drugs. One way they could do this would be to encourage retail pharmacy participation in the Medicaid program by permitting them to retain profits from the sale of listed drugs to Medicaid recipients. Other alternative payment systems could include, for example, contracting on a competitive basis for pharmaceutical services with selected pharmacies to which recipients may go for drugs without incurring a copayment or a system which entails charge screens and/or mandatory discounts. Additionally, State agencies may initiate or retain already existing so-called "mini-MAC" programs, which they have established on specific drugs either at levels lower than those established under the current Federal MAC limits or on drugs not now covered by MAC limits. This system of aggregate upper limits will allow State agencies to alter payment rates for specific listed drugs without first having to obtain permission from HCFA. The agencies then will be able to respond rapidly to sudden price fluctuations, which may threaten the supply of specific drugs on the HCFA list, without having to pursue a cumbersome approval process. A final advantage of the aggregate limit methodology is the ease of administration at the Federal level and the lack of administrative burden on State programs.

A. Multiple Source Drugs

The Federal upper limit standard that we have adopted for certain multiple source drugs is based on an aggregate payment amount equal to an amount that includes the ingredient cost of the drug calculated according to the formula described below and a reasonable dispensing fee. HCFA will determine to which drugs the formula will be applied. The listing of these drugs and any revisions to the list will be provided to State agencies through Medicaid program issuances on a timely, periodic basis (possibly semi-annually). The effective date of the new prices will be subsequent to the issuance of the listing. As did the NPRM, the final rule will specify that the drugs to which this formula will be applied must have been evaluated as therapeutically equivalent by the FDA. Similar to the NPRM, the final rule will specify that at least three suppliers list the drug in a national compendium. The NPRM stated that three suppliers would advertise the drug in the *Red Book* or *Blue Book*.

The formula to be used in calculating the upper limit of payment for certain multiple source drugs will be 150 percent of the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules (or if the drug is not commonly available in quantities of 100, the package size commonly listed), or in the case of liquids, the commonly listed size. As we stated in the NPRM, we chose the markup of 150 percent in order to meet the following two objectives: (1) That the markup be high enough to assure that pharmacists can normally obtain and stock an equivalent product without losing money on acquisition costs of incurring the expense of departure from normal purchasing channels, and (2) that the markup not be so high as to cost the Medicaid program unnecessary money. In other words, the 150 percent is intended to balance the interests of both pharmacists and the government in achieving efficiency, economy and quality of care as specified in section 1902(a)(30) of the Act.

In the NPRM, we stated that we would use the *Red Book* or *Blue Book* to determine the least costly therapeutic equivalent that can be purchased by pharmacists. In this final rule, however, we are deleting the reference to these specific sources and are specifying that we will publish and use the list of all current editions (or updates) of acceptable published drug compendia available for sale nationally. Although State agencies will need to calculate or impute a dispensing fee (if they do not pay for the dispensing fee separately) in order to determine if they meet the upper limit standard for certain multiple source drugs, we are deleting the current § 447.333 that recommends how agencies are to establish the dispensing fee.

As originally proposed under all options, this final rule will provide that if a physician certifies that a brand name drug is medically necessary, the upper limit for payment based on the formula will not apply. The upper limit for payment of "other drugs" (discussed in section IV.B.) will apply.

In the future, the formula approach to setting an upper limit will be evaluated. We are aware of several State agencies now in the process of negotiating competitive bids for discounts or rebates from drug manufacturers and suppliers. Other agencies are considering selective contracting with providers or pharmacies (preferred provider organizations). Additionally, the interaction of competitive pricing and creative marketing may cause dynamics in the market that would necessitate a revision of our policy. Thus, we will monitor the implementation of this

policy, as well as the various payment systems used by State agencies and the dynamics of the marketplace, in order to make timely revisions to the policy for Medicaid upper limits for drug payments.

B. Other Drugs

In this final rule, we specify that the agency payment for certified brand name drugs and drugs other than multiple source drugs for which a specific limit has been established must not exceed, in the aggregate, the level of payment calculated by applying the lower of (1) the EAC plus a dispensing fee; or (2) the provider's usual and customary charges to the general public.

Under these rules, the Federal requirement for States to use the EAC method of payment will be eliminated. However, because the rule merely establishes an upper limit concept and does not describe the specific methodology for payment, State agencies may continue their practice of establishing EACs for the ingredient costs and adding to it a dispensing fee. Such practices will be acceptable, as will a system of establishing charge/payment screens based on Statewide or regional customary and usual prices.

The State's findings in regard to whether the Statewide aggregate upper limit test is met must demonstrate that aggregate payments do not exceed payment as calculated under the EAC principles.

C. State Plan Requirements, Findings and Assurances

We are revising the proposed language concerning State agency assurances regarding drug payment systems. We are clarifying that all agencies, regardless of the payment system used, will be required, in accordance with § 447.333(b)(1) of this final rule, to make two separate and distinct findings that expenditures for listed multiple source drugs on the one hand, and for all other drugs on the other, under their payment methodology will not exceed the upper limits established by HCFA. All State agencies will be required to maintain the supporting documentation and to provide HCFA with an assurance that they have made the required findings.

We note that we also have changed the requirements for findings and assurances to differ with regard to each drug category. We will require an annual finding for multiple source drugs and a triennial finding for all other drugs. The findings for multiple source drugs will be required at least annually because the State agencies efforts will be directed primarily at comparing State payments, in the aggregate, to the maximum ingredient costs published by HCFA. However, for all other drugs, State agencies will first have to determine the estimated acquisition costs before making comparisons on the aggregate basis. It is because of the various activities States will need to pursue in order to make the findings for all other drugs that we are requiring that this be done at least every three years. We anticipate that the triennial findings and assurances for all other drugs will lessen the administrative/reporting burdens on State agencies and maintain a level of accountability for purposes of FFP.

Apart from the initial plan submission, and subsequent assurances, an agency, which has determined that it is adopting a new methodology or making significant changes in its payment rates or to its existing system, will be required to provide HCFA with the requisite State plan amendments and the assurance that it has made the necessary findings.

D. Other Changes

As proposed, this final rule will remove the Departmental rules at 45 CFR Part 19 that limit drug reimbursement under certain Federal health programs. These rules have little impact upon programs other than Medicaid, and the Medicaid regulations concerning upper limits for drug payments are being revised under this final rule. We also are deleting cross references to 45 CFR Part 19 contained in 42 CFR 430.0(b)(2)(ii) and 45 CFR 1.2, and the reference to MAC limits in 42 CFR 413.110.

V. Regulatory Impact Statement

A. Introduction

Executive Order (E.O.) 12291 requires us to prepare and publish a final regulatory impact analysis for any final regulation that meets one of the E.O. criteria for a "major rule"; that is, that would be likely to result in: An annual effect on the the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The local character of retail pharmaceutical markets, the large number of parties that participate in those markets, the variety of products sold, the numerous distribution channels through which these products flow, and a general lack of data adequately describing these various aspects of the market all make it extremely difficult for us to determine how and to what degree this final rule will affect market participants. For these reasons, we cannot say with any degree of certainty whether this rule will meet or exceed the Executive Order's criteria for a major rule. However, because of its controversial nature, we are providing a regulatory impact analysis.

In addition, we generally prepare a final regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a final regulation will not have a significant economic impact on a substantial number of small entities. Although the most direct effect of this rule will be on States, States are not small entities under the RFA. The economic size of Medicaid participating retail pharmacies range from large national corporate chains to small independent single-owner outlets. Yet because retail pharmaceutical markets appear to be largely local in nature, retail pharmacies operate in these markets as small entities. For purposes of the RFA, therefore, we consider pharmacies to be small entities. Other entities that may be affected by this final rule, for example, wholesale distributors and manufacturers, also may qualify as small entities under the RFA, but are more likely to participate in regional or national markets, and thus, are more likely to take on the characteristics of large firms. For this reason, plus the fact that this rule is not explicitly directed at these other entities or expected to affect them directly, we are not considering them as small entities for purposes of this rule.

B. Objectives

Through promulgation of this final rule, we hope to achieve several objectives we view as essential for providing acceptable care to Medicaid recipients and for increasing the efficiency with which pharmaceutical products and services are delivered to recipients. These objectives are to:

- Establish simple, administrable methods of applying two separate and distinct upper limits on State Medicaid expenditures: one for certain therapeutically equivalent multiple source drugs, and one for all other drugs
- Promote wider and more efficient distribution of pharmaceutical products and services, and avoid potential disruptions in the supply of drug

products that appear to be a major drawback of the present method of reimbursing retail pharmacists under the MAC program.

• Conserve scarce Federal and State resources through encouraging the more judicious purchasing of pharmaceuticals on behalf of Medicaid recipients, thus achieving some budget savings, while preserving or enhancing current levels of service.

In pursuing these objectives, we also wish to give State agencies the incentive to encourage prudent purchasing practices on the part of retail pharmacists and foster price competition among wholesale suppliers and manufacturers of multiple source drugs.

C. Impact on State Agencies

The aggregate payment limit on HCFA listed drugs as well as the general limit on sole-source and non-listed multiple source drugs, afford State agencies wide latitude in developing their own payment schemes to suit local conditions and unusual circumstances that may arise from time to time. For example, State agencies may retain already existing so called "mini-MAC" programs, which they have established on specific drugs either at levels lower than those established under the Federal MAC limits or on drugs not now covered by MAC limits. Also, under the aggregate limits, State agencies are free to experiment with alternative payment systems, for example, letting contracts on a competitive basis for pharmaceutical services with selected pharmacies to which recipients may go for drugs without incurring a copayment, or systems identical or similar to PhIP or CIP. This system will also allow States to alter payment rates for specific listed drugs without first having to obtain permission from HCFA. States then will be able to respond rapidly to sudden price fluctuations which may threaten the supply of specific drugs on the HCFA list without having to pursue a cumbersome approval process. A final advantage of the aggregate limit methodology is ease of administration at the Federal level and the lack of administrative burden on State programs.

D. Small Entities Affected

The drug industry is highly complex and multi-layered, with a variety of manufacturing, distribution, and retail sales arrangements that not only differ according to geographic location, but also vary by product. Further, under the Medicaid program, the immediate payor (that is, the State) is distinct from the purchaser (usually the recipient) or the orderer (the physician), both of whom are key decision makers for each specific purchase of drugs. These rules will directly affect only the State, and even then, these rules do not control the option available to the State, but establish limits on the extent that we will share in the State's overall expenditures for covered drugs. It is each State's actions, taken in some measure in response to these upper limits, that will in turn affect other parties.

As a result, it is difficult for us to clearly identify the entities affected by these regulations, and nearly impossible to fix the magnitude of any impact. At best, we can only identify broad categories of small entities that may be affected in some fashion by this rule, such as retail drug outlets and pharmacists, wholesale drug distributors, and manufacturers.

Through requiring States to establish programs to make payments which reflect the availability of lower cost alternatives when three or more therapeutically equivalent generic alternatives are available, this rule will affect the behavior of retail pharmacists who receive Medicaid payments. As a result of the response of pharmacists to State programs, we expect there to be effects on drug manufacturers and wholesale distributors. Also, it is conceivable that this rule might make physicians more aware of the availability of low cost generic drugs that could be substituted for higher cost leading brand drugs, and thus produce changes in physician prescribing practices. Furthermore, by making payments more prudent, we hope to affect Medicaid recipients positively by improving the States' and Federal government's financial ability to provide for needed services.

E. Expected Impact of Limits Placed on Listed Drugs

1. Increased State Flexibility

As described in section IV of this preamble and in §§ 447.332(a) and 447.331 of the rule, HCFA will prescribe aggregate upper limits on certain therapeutically equivalent multiple-source drugs we determine to be readily available, and on sole source and other multiple-source drugs. The limit for readily available drugs is to be based on 150 percent of the lowest known price for each drug on the list. The limit for sole source and other multiple-source drugs will be based on the amounts paid by other payors. Since we are setting separate aggregate limits on what we are calling "listed drugs" and on "other drugs", States will be free to make payments for individual drugs on any reasonable basis as long as total payments for each group of drugs do not exceed the aggregate limit on that group. This approach should help avoid disruptions in the supply of listed drugs in circumstances in which acquisition costs may exceed the listed price used in establishing the HCFA limits.

State agencies should determine, independent of the 150 percent formula, appropriate payment levels for the listed multiple-source drugs. We would not expect a State agency to adopt directly the upper limit methodology as a payment method because it does not gear payments to markups appropriate to the actual costs of acquiring and dispensing these drugs. Under these final regulations, State agencies will be able to make higher payments for some listed drugs as long as they pay at rates lower than those listed for other drugs on the list. By providing this measure of flexibility, we expect that State agencies will be able to ensure that listed drugs will be generally available to recipients.

As a counterpart to allowing State agencies the freedom to set their own minimum price floor on drugs in order to cover pharmacists' ingredient costs, they also have the authority to set an upper limit on the mark-up of specific drugs on the HCFA list. Since we are not placing maximum payment limits on individual drugs, drugs with high compendia prices could generate extremely high payment levels. Unless an agency's payment methodology ensured otherwise, a Medicaid agency could end up paying inappropriately high rates for some drugs while still being in compliance with the aggregate upper limit. Nevertheless, we believe States may establish maximum payment limits in order to offset the minimum payment levels necessary to ensure reasonable compensation for very low priced drugs.

Similarly, State agencies may employ essentially the same approach in meeting the limits for all other drugs. That is, the same principal of balancing payment increases for some drugs with decreases for other drugs also applies in determining whether aggregate payments exceed the limit. For reasons of economy, availability, or therapeutic efficacy, a State agency may want to raise or lower the amount it pays for certain drugs in efforts to influence the supply of specific drugs. Under the aggregate limit methodology any change in payments above or below the lower of the EAC or customary charges for specific drugs must be balanced with a corresponding reduction or increase in payments for other drugs within the all "other drugs" payment category.